

REMARKS

According to the Office Action of January 4, 2008, claims 13, 15-29, 32 and 33 have been examined on their merits, and objected to and/or rejected. In response, Applicants amend claims 13, 20, 24-28, 32 and 33, and add new claims 34-36. No new matter has been added by this Amendment. In view of these amendments and the remarks below, Applicants respectfully request that the asserted rejections be reconsidered and withdrawn.

Priority

On page 2, the Office Action contends that claim 33 is not supported by the priority application (EP App. No. 02078684.4). Claim 33, as amended, recites: "The food composition according to claim 28, wherein the α -glucan contains α (1,3) and α (1,6) linkages." This claim is supported by EP App. No. 0207864.4 at paragraph 24, which states:

The glucans to be used according to the invention contain, as a result of their branched nature, at least two types of linking one AGU to another. The type may be 1,2-linking, 1,3-linking, 1,4-linking or 1,6-linking. *The glucans may also contains 1,3 and 1,6 linkages* ...[Emphasis added.]

Since the priority application provides support for a food composition wherein the α -glucan contains α (1,3) and α (1,6) linkages, claim 33 should be afforded the benefit of the priority application's filing date. For this reason, Applicants respectfully request that this objection be withdrawn.

Information Disclosure Statement

On page 3, the Office Action states that "[o]nly the English abstracts of documents 6, 8, 13 and 14 of the IDS submitted September 4, 2007 were considered." Applicants request that appropriate consideration of these documents be made. According to MPEP § 609.05(b),

The information contained in information disclosure statements which comply with both the content requirements of 37 CFR 1.98 and the requirements, based on the time of filing the statement, of 37 CFR 1.97 will be considered by the examiner. Consideration by the examiner of the information submitted in an IDS *means that the examiner will consider the documents in the same manner as other documents in Office search files are considered by the examiner while*

conducting a search of the prior art in a proper field of search. ... [Emphasis added.]

Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted (see MPEP § 609.04(a), subsection III.) *and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches.*

Accordingly, Applicants request that documents 6, 8, 13 and 14 be considered in the same manner as other documents in Office search files, and that the drawings, among other things, be considered as well.

Objection to Claim 13

Claim 13 has been objected to because “satiety” and “satiation” were considered synonyms. Applicants respectfully disagree. Satiety is the state of being satisfactorily full and unable to take on more, whereas satiation is the act of achieving full gratification. According to Blundell *et al.* (“Regulation of appetite: role of leptin in signaling systems for drive and satiety,” *Int. J. Obes. Relat. Metab. Disord.* (2001) 25 Supp. 1: S29-S34.), satiation can be regarded as the complex of processes that brings eating to a halt, while satiety can be regarded as those events that arise from food consumption and that serve to suppress hunger (the urge to eat) and maintain an inhibition over eating for a particular period of time. According to McDuffie *et al.* (“Effects of exogenous leptin on satiety and satiation in patients with lipodystrophy and leptin insufficiency,” *J. Clin. Endocrinology & Metab.* (2004) 89(9): 4258-4263), “satiation (meal termination) is defined as the point at which an individual becomes full or sated during an isolated eating episode, and satiety (inter-meal interval) is defined as the period during which an individual remains sated after the ingestion of a prescribed amount of food,” (at PS. 4258).

Thus, satiety and satiation are not the same, and both can be induced. For this reasons, Applicants respectfully request that this objection be withdrawn.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 13, 19 and 27 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. It is believed that claim 19 was inadvertently recited in this

rejection because claim 19 does not recite "where the α -glucan is used in a concentration of 1-10% by weight." This limitation is recited in claim 20; therefore, it is believed that this rejection was intended for claim 20 rather than claim 19.

The rejection asserted against claim 13 relates to the recitation of "an effective amount." Because "an effective amount" has been deleted from claim 13, withdrawal of the rejection against claim 13 is respectfully requested.

The Office Action contends that claim 20 is unclear. Amended claim 20, which now depends from claim 34, recites that the liquid contains α -glucan at a concentration of 1-10% by weight. Accordingly, withdrawal of the rejection against claim 20 is respectfully requested.

The rejection asserted against claim 27 based on interpreting claim 28's α -glucan as one compound. Claim 28 has been amended to recite "[a] food composition comprising ... at least one branched α -glucan" Thus, claim 28 now recites that there can be more than one α -glucan. Accordingly, reading claim 27 to include a second α -glucan would not be indefinite. For this reason, withdrawal of this rejection is respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 13, 15-21, 23-26, 28 and 32 have been rejected under 35 U.S.C. § 102 as anticipated by a typical carnivorous diet as evidenced by Unisa.edu and Elmhurst.edu.

The Patent Office must establish that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Thus, the Patent Office must establish that the reference is prior art. According to MPEP § 2128, "prior art disclosures on the Internet or on an on-line database are considered to be publicly available as of the date the item was publicly posted." In this case, there is no evidence that either reference pre-dates the priority date of this application. Therefore, a *prima facie* case of anticipation has not been established. For this reason, reconsideration and withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 13, 15-29 and 32 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Van Geel-Schutten *et al.* (Applied and Envir. Microbiol., (1999) 65(7): 3004-3014). The present invention is directed to a method of inducing satiety and satiation by administering a branched α -glucan having a degree of branching of at least 8%. On pages 6-7, the Office Action contends that this invention obvious in view of Van Geel-Schutten, but does not establish that Van Geel-Schutten teaches the recited degree of branching, or that this would be obvious to one of ordinary skill in the art. Thus, the Office Action fails to establish a *prima facie* case of obviousness based on Van Geel-Schutten.

On page 6, the Office Action contends that Van Geel-Schutten teaches that polysaccharides (cellulose, pectin, and starch) are used in the food industry, and that exopolysaccharides (EPS) produced from lactic acid bacteria are more desirable because these EPSs are produced by food-grade organisms with GRAS ("generally recognized as safe") status. Van Geel-Schutten states that

A variety of high-molecular weight polysaccharides produced by plants ..., seaweeds ..., and bacteria ... find applications as ***viscosifying, stabilizing, emulsifying, gelling or water-binding agents*** in food and nonfood industries [citations omitted]. All of these polysaccharides are ***additives***, however, and therefore they are considered less desirable in the food industry.

Lactic acid bacteria are food-grade organisms that possess GRAS (generally recognized as safe) status and are known to produce an abundant variety of exopolysaccharides (EPS) molecules [citations omitted], which ***contribute to the texture*** of fermented milk. [Emphasis added.]

Van Geel-Schutten at page 3008.

Unlike the recited invention, Van Geel-Schutten does not teach inducing satiety and satiation without increasing caloric intake. Thus the recited invention is not obvious because there is no suggestion in Van Geel-Schutten and that one of ordinary skill in the art would not recognize that a branched α -glucan having an average molar weight of at least 10^5 Da and having a degree of branching of at least 8% would induce satiety and satiation without increasing caloric intake. Additionally, the invention recited in claims 15, 24 and 25 is not obvious because there is no suggestion in Van Geel-Schutten or that one of ordinary skill in the art would recognize that a branched α -glucan having an average molar weight of at least 10^5 Da and having a degree of

branching of at least 10% or at least 12% and up to 24% would induce satiety and satiation without increasing caloric intake.

Additionally, Van Geel-Schutten cannot be used to support a rejection under 35 U.S.C. § 103 because it is non-analogous prior art. Van Geel-Schutten is directed to modifying the texture of fermented milk with EPS, not inducing satiety and satiation. Thus, there is no reason for a person of ordinary skill in the art even to consider Van Geel-Schutten when working on the recited invention.

On page 6, the Office Action acknowledges that Van Geel-Schutten does not explicitly teach a food composition comprising reuteran, as recited in claim 27, or a composition comprising at least 1-10% or at least 1% α -glucan or reuteran as recited in claims 20 and 28. In order to establish that these elements are obvious, the Patent Office must either establish that they are inherently disclosed in a reference, or take official notice of these elements.

In order to establish an inherent disclosure, the Patent Office must establish that the missing element is "necessarily present," not merely probably or possibly present, in the reference. *Rosco*, 304 F.3d at 1380, *quoting Trintec Indus., Inc. v. Top U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed.Cir. 2002), *citation omitted*. Here, the Office Action makes no attempt to establish that these elements are necessary.

"In limited circumstances, it is appropriate for an examiner to take official notice of facts not in the record or to rely on 'common knowledge' in making a rejection, however such rejections should be judiciously applied." MPEP § 2144.03. These circumstances are even more limited when there is no documentary evidence to support the assertion that the officially noted limitation is common knowledge within the art. MPEP § 2144.03. "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of *instant and unquestionable* demonstration as being well-known." MPEP § 2144.03 (emphasis added).

The Office Action also makes no attempt to demonstrate that these missing elements are well-known within the art. For these additional reasons, the Office Action has not established a *prima facie* case of obviousness for dependent claims 20, 27 and 28.

Claims 13, 15, 16, 18-22, 24, 28, 29, 32 and 33 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,786,196 to Cote *et al.* ("Cote"). On page 8, the Office Action contends that Cote teaches a high-molecular weight alternan consisting primarily of α -1,3 linked and α -1,6 linked glucose residues. However, Cote is actually directed to low-molecular weight fractions. In column 2, lines 38-43, Cote states that its inventors "discovered a new enzyme, alternanase, which is effective for the endo-hydrolytic cleave of alternan, producing a thinned composition of low molecular weight fractions, which exhibit reduced viscosity and increased solubility relative to native alternan." The average molecular weight of these oligosaccharides is well below 10^5 Da because of the production of relative large amounts of mono-, di- and trisaccharides as well as cyclic tetrasaccharides. Thus, Cote does not teach using a composition having an average molar weight of at least 10^5 Da.

On page 8, the Office Action contends that Cote teaches an alternan with approximately 10% branching, and cites Cote column 1, lines 10-17:

The polysaccharide alternan was first described by Jeanes *et al.* [citation omitted] as one of two extracellular α -D glucans, referred to as fraction S, produced by *Leuconostoc mesenteroides* NRRLB-1355. The structure of this fraction was later determined by Misaki *et al.* [citation omitted] to consist primarily of an alternating sequence of α -1,3-linked and α -1,6-linked D-glucose residues, with approximately 10% branching.

However, Cote does not teach that the alternan can be used to induce satiety and satiation without increasing caloric intake. With regard to claims 17 and 26, Cote does not disclose α -1,4 linked and α -1,6 linked polysaccharides, or α -1,4,6 linked polysaccharides. With regard to claim 25, which is directed to using α -glucan with at least 12% and up to 24% branching, Cote does not teach an α -glucan with this degree of branching. With regard to claim 23, Cote does not teach an aqueous solution of 7.5 wt.% of the recited α -glucan at pH 2, which shows an increase in viscosity of at least 1.5 times compared to the viscosity at pH 6.8. Since the Office Action does not address these deficiencies, the Office Action has not established a *prima facie* case of obviousness in view of Cote.

For these reasons, Applicants respectfully request reconsideration and withdrawal of this rejection.

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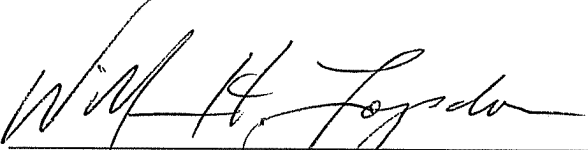
Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that pending claims 13, 15-29, 32 and 33 in the instant application are patentable over the prior art and are in condition for allowance. Accordingly, reconsideration and withdrawal of the rejections and objections is respectfully requested. Applicants also believe that new claims 34-36 are patentable over the prior art and are in condition for allowance. Accordingly, allowance of claims 13, 15-28 and 32-36 is respectfully requested.

Should the Examiner have any questions or concerns, the Examiner is invited to contact Applicants' undersigned attorney.

Respectfully submitted,

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